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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,506	04/22/2004	Marvin John Cervantes	P1482 US (2650/81)	7331

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EXAMINER	
POUS, NATALIE R	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,506	CERVANTES, MARVIN JOHN	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/22/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The term "invention" should be avoided in the abstract. Appropriate correction is required.

Claim Objections

Claim 15 is objected to because of the following informalities: claim 15 is a copy of claim 12. Only one copy of each claim should be submitted. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 11, 12, 15, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts et al. (US 5984964).

Regarding Claim 11, Roberts teaches a protective sleeve (20) for a stent assembly (14), comprising: A hollow tube (20) having a proximal outer diameter (25), a medial inner diameter (L7), and a distal inner diameter (L5), wherein the distal inner diameter is sufficient to encircle an outer diameter of the stent assembly (fig. 1), and wherein the distal inner diameter is open, and wherein the sleeve retractably covers the stent deployment assembly (fig. 1a).

Regarding Claims 12 and 15, Roberts teaches the sleeve of claim 11 wherein the sleeve has a distal inner diameter of substantially 0.071 centimeters, a distal outer diameter of substantially 0.0825 centimeters (Column 4, proximate lines 52-59), a medial inner diameter (L7) of 0.045 centimeters, and a medial outer diameter of 0.055 centimeters (Column 4, proximate lines 59-63).

Regarding Claim 18, Roberts teaches the system of claim 11 wherein the sleeve comprises a material selected from the group consisting of nylon, polyurethane, polyethylene terephthalate, polyethylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, an elastane, a thermoplastic elastomer, a woven polymeric fabric, an expandable polymeric sheet and a material that dissolves while in a vasculature (Column 2, proximate lines 45-47).

Claims 11, 16 and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Fiedler (US 6605109).

Regarding Claim 11, Fiedler teaches a protective sleeve (36) for a stent assembly (50), comprising: A hollow tube (36) having a proximal outer diameter, a medial inner diameter, and a distal inner diameter, wherein the distal inner diameter is sufficient to encircle an outer diameter of the stent assembly (fig. 1), and wherein the distal inner diameter is open, and wherein the sleeve retractably covers the stent deployment assembly (fig. 3).

Regarding Claim 16, Fiedler teaches he sleeve of claim 11 further comprising a lubricious coating on at least a portion of a surface of the sleeve (Column 7, proximate lines 12-17).

Regarding Claim 17, Fiedler teaches the sleeve of claim 11 wherein the lubricious coating comprises a material selected from the group consisting of phosphorylcholine, a hydrophilic coating, and a lubricious film (Column 7, proximate lines 12-17).

Claims 1-4 11, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al.

Regarding Claim, Fischell teaches a system for treating a vascular condition, comprising: a catheter (12); a stent assembly (40) coupled to the catheter; the stent assembly comprising a coated stent including a stent framework and a drug coating disposed on at least a portion of the stent framework (Column 5, proximate lines 32-34); and a protective sleeve (34) removably covering the stent deployment assembly and at least a portion of the catheter, wherein said sleeve comprises a hollow tube having a proximal outer diameter, a medial inner diameter, and a distal inner diameter (fig. 2d); and wherein the distal inner diameter is sufficient to encircle an outer diameter of the stent deployment assembly (fig. 2b), and wherein the medial inner diameter is sufficient to encircle an outer diameter of the catheter, and wherein the distal inner diameter is open (fig. 2b), wherein the protective sleeve is removed from covering the stent framework prior to deploying the stent (fig. 2c).

Regarding Claim 2, Fischell teaches the system of claim 1 further comprising a port to a vessel (38), wherein the port comprises a toughy lock (30), wherein the toughy lock further comprises an o-ring (37) having an o-ring inner diameter, wherein the proximal outer diameter of the sleeve is greater than the o-ring inner diameter (fig. 1).

Regarding Claim 3, Fischell teaches the system of claim 1 further comprising a guide wire (250), and wherein the sleeve further comprises a guide wire notch (208), wherein the guide wire extends longitudinally through the guide wire notch (fig. 7).

Regarding Claim 4, Fischell teaches the system of claim 3 wherein the guide wire notch extends at least part of the distance from an outer surface of the sleeve through an inner surface of the sleeve (fig. 7).

Regarding Claim 11, Fischell teaches a protective sleeve (34) for a stent assembly (40), comprising: A hollow tube (34) having a proximal outer diameter, a medial inner diameter, and a distal inner diameter, wherein the distal inner diameter is sufficient to encircle an outer diameter of the stent assembly (fig. 2d), and wherein the distal inner diameter is open, and wherein the sleeve retractably covers the stent deployment assembly (figs. 2a-2c).

Regarding Claim 13, Fischell teaches the sleeve of claim 11 wherein the sleeve (34) has an outer diameter that is greater than the inner diameter of an o-ring of a toughy lock, and wherein the sleeve can not pass the o-ring of the toughy lock during deployment of the stent assembly (fig. 1).

Regarding Claim 14, Fischell teaches the sleeve of claim 11 wherein the sleeve has an outer diameter that is less than the inner diameter of an o-ring of a toughy lock (it is noted that the o-ring and toughy lock are not positively claimed, and thus the sleeve has an outer diameter that is less than the inner diameter of any o-ring that is larger than the sleeve, and it is known that o-rings are formed in many sizes), and wherein the sleeve passes the o-ring of the toughy lock during deployment, and wherein

the sleeve is removed from the stent assembly at a site where the stent is to be deployed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5, 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts in view of Fischell.

Roberts teaches a system for treating a vascular condition comprising the following: A catheter (8) a stent assembly (14) coupled to the catheter; the stent assembly comprising a stent framework; and a protective sleeve (20) removably covering the stent deployment assembly and at least a portion of the catheter, wherein said sleeve comprises a hollow tube having a proximal outer diameter (25), a medial inner diameter (L7), and a distal inner diameter (L5); and wherein the distal inner diameter is sufficient

to encircle an outer diameter of the stent deployment assembly (fig. 1), and wherein the medial inner diameter is sufficient to encircle an outer diameter of the catheter, and wherein the distal inner diameter is open, wherein the protective sleeve is removed from covering the stent framework prior to deploying the stent (fig. 1a).

wherein the sleeve has a distal inner diameter of substantially 0.071 centimeters, a distal outer diameter of substantially 0.0825 centimeters (Column 4, proximate lines 52-59), a medial inner diameter (L7) of 0.045 centimeters, and a medial outer diameter of 0.055 centimeters (Column 4, proximate lines 59-63).

wherein the sleeve comprises a material selected from the group consisting of nylon, polyurethane, polyethylene terephthalate, polyethylene, polytetrafluoroethylene, expanded polytetrafluoroethylene, an elastane, a thermoplastic elastomer, a woven polymeric fabric, an expandable polymeric sheet and a material that dissolves while in a vasculature (Column 2, proximate lines 45-47).

Roberts fails to teach wherein the stent comprises a drug coating disposed on at least a portion of the stent framework. Fischell teaches a stent coated in a drug in order to reduce the risk of thrombosis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Roberts with a drug disposed on the stent as taught by Fischell in order to reduce the risk of thrombosis.

Claims 1, 7 and 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Fiedler in view of Fischell.

Fiedler teaches a system for treating a vascular condition comprising the following:

A catheter (22) a stent assembly (50) coupled to the catheter; the stent assembly comprising a stent framework; and a protective sleeve (36) removably covering the stent deployment assembly and at least a portion of the catheter, wherein said sleeve comprises a hollow tube having a proximal outer diameter, a medial inner diameter, and a distal inner diameter; and wherein the distal inner diameter is sufficient to encircle an outer diameter of the stent deployment assembly (fig. 1), and wherein the medial inner diameter is sufficient to encircle an outer diameter of the catheter, and wherein the distal inner diameter is open, wherein the protective sleeve is removed from covering the stent framework prior to deploying the stent (fig. 3).
wherein the sleeve comprises a lubricious coating comprising a material selected from the group consisting of phosphorylcholine, a hydrophilic coating, and a lubricious film (Column 7, proximate lines 12-17).

Fiedler fails to teach wherein the stent comprises a drug coating disposed on at least a portion of the stent framework. Fischell teaches a stent coated in a drug in order to reduce the risk of thrombosis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Fiedler with a drug disposed on the stent as taught by Fischell in order to reduce the risk of thrombosis.

Claim 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell in view of Sgro. Fischell teaches all limitations of preceding dependent claim 1, but fails to teach wherein the sleeve comprises a material that dissolves while in a vasculature. Sgro teaches a sheath for covering a stent system wherein the sheath dissolves in the

vasculature in order to protect the stent during deployment, and not require mechanical removal such that there is less chance of malfunction. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Fischell as taught by Sgro in order to protect the stent during deployment, and not require mechanical removal such that there is less chance of malfunction.

Claims 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell as a matter of design choice.

Claim 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Fischell as a matter of design choice. Fischell teaches all limiations of preceding dependent claim 1, and further teaches wherein the port comprises a toughy lock, wherein the toughy lock further comprises an o-ring that comprises an o-ring inner diameter, but fails to teach wherein the proximal outer diameter of the sleeve is less than the o-ring inner diameter. It would have been an obvious matter of design choice to adjust the diameter of the o-ring or the sleeve since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-

6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
2/9/07

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SUPERVISORY PATENT EXAMINER
2/12/07